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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/583,016

Applicant(s)

SHASTRI ET AL.

Examiner

Alicia M. Toscano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
- Paper No(s)/Mail Date 11/03/08 6/15/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 23, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Applicant's wording of a molar ratio from about 5 to about 120 (and the like in the respective claims) is indefinite because "5" is not a ratio and as such it is unclear what Applicant is referring to. A molar ratio of 5:120 does not seem consistent with the claimed invention since the lactone component seems to be desired in an amount greater than that of the diol core. As such it is unclear what is required by the limitation.
3. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. It is unclear what the scope of the ranges of these claims are meant to encompass. There are no requirements or limitations as to what constitutes the lactone "unit" of claim 5. As per the formula of claim 5, there are 2 lactone units, each repeated at least 4 times (so 8 'units' total), 1 initiating core and 1 coupling unit. As such the lactone unit always inherently constitutes 80% (8/10 unit parts)

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of the polyester. It is unclear, given the definitions of the units in the claims, how one can have 10-99% of said unit in the polyester backbone.

Claim Objections

5. Claim 5 is objected to because of the following informalities: Applicant should keep the symbols constant throughout the claims, the "D" unit of the formula is inconsistent with the "C" coupling unit and correction is required. The correction should be in scope with claim 15, which uses "D". Appropriate correction is required.

6. Claims 10-12 are objected to because of the following informalities: the lower end of the ranges therein is 50. Propiolactone, the lowest MW lactone claimed, has a MW of 72. It is unclear how one can have a unit MW of 50. Appropriate correction is required.

7. Claim 28 is objected to because of the following informalities: depsipeptide is not a lactone, as such calling it a lactone member is improper. Appropriate correction is required.

8. Claim 36 is objected to because of the following informalities: in line 1 the spelling of agent should be corrected. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinu (US 5202413).

Spinu discloses alternating ABAN polylactide block copolymers (title). The "A" block comprises lactide units derived from ring opening lactones such as those disclosed in Column 4. The "B" block is a diol having a number average MW of 500-20,000 and may be a dihydroxy ether such as polyethylene oxide and the like (Column 3 lines 25-69 and examples). The "N" coupling unit, which links ABA block copolymers together, may be diacyl chlorides having 8-20 carbon atoms, which encompasses sebacic acid, dodecanoic acid and the like, is disclosed in Column 5 line 15. Catalysts such as stannous 2-ethylhexanoate are used to react the diol with the lactone (Column 4 lines 61-62). The composition above meets the requirements of claims 1, 2, 3, 7, 13, 14, 15, 16, 19, 20, 21, 22, 26, 27, 28, 29, 30-32. Since the composition requirements of the claims are met the properties of claims 4 and 18 are found to be inherently met by the composition. Since there is no requirement in claim 5 as to how to define the lactone units, and since the MW of the blocks is at least 500, preferably at least 2000 which given a lactic acid MW of 93 means at least 5 to 20 lactic acid

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monomers are present, the m requirements of claims 5 and 6 are deemed met. The number of units linked by the coupling agent can be from 1 to 100 (Column 3 line 16), as further required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, $8/10=80\%$) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12. The end product has a number average MW of 10,000-250,000 (Column 5 line 27), since the weight average MW is higher than the number average MW the range of claim 17 is met therein. Since the end MW and the lactone unit requirements of the claim are met it is the Examiner's position that the molar ratio is inherently met by Spinu, additionally, Ex 2 discloses a molar ratio of 71:1, Ex 3 discloses a molar ratio of 23:1, Ex 9 discloses a molar ratio of 14:1, as such the limitations of claims 23 and 24 are deemed met. The coupling agent added in a 1:1 ratio Column 5 line 17, as required by claim 25. Since there is no structural limitation of a device required in the claims the Examiner finds the end molded resins to meet the requirements of claim 33. Since there is no disclosure as to how one adapts the device in claims 34 and 35 the Examiner finds the mere molding of an article to meet the adaptation requirement and finds the limitations of the claims met.

10. Claims 1-14, 18-20, 22-25, 27-30 and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Fowler (US 2977385).

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Fowler discloses lactone polymers. Said polymers are ABA type polymers (Column 1 lines 19-25) which are further chain extended with diisocyanates (Column 9 lines 19-21). The A block is derived from substituted or unsubstituted caprolactones (Column 1 lines 68-71), the B block is derived from diols such as ethylene glycol, polyethylene glycol and the like (Column 3 lines 10-15), and the composition may be further reacted with diisocyanates to form higher molecular weight products (Column 9 lines 19-24). The lactone and the diol are reacted in the presence of a catalyst such as 2-ethylhexanoic acid. The elements above meet the requirements of claims 1, 2, 3, 7, 13, 14, 19, 20, 22, 27, 28, 29 and 30. Since the composition requirements are met the properties of claims 4 and 18 are deemed inherently met by the composition. The molar proportions are selected to obtain the desired MW, and a 10:1 lactone to diol ratio is disclosed in Column 10 line 75, as required by claims 23 and 24. The molar ratio of the terminating acid and the ABA polymer may be equivalent, or 1:1 (Column 10 lines 24-27), as required by claim 25, the molar ratio of 10:1 would give 10 lactone repeat units, as required by claims 5 and 6. Since the molar ratios are met it is the Examiner's position one would inherently get the "x" number of repeat units additionally required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, $8/10=80\%$) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12. Since there is no structural limitation of a device required in the claims the Examiner finds the end molded resins to meet the

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requirements of claim 33. Since there is no disclosure as to how one adapts the device in claims 34 and 35 the Examiner finds the mere molding of an article to meet the adaptation requirement and finds the limitations of the claims met.

11. Claims 1-18, 20-22 and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn (US 5711958).

Cohn discloses polymeric compositions comprising chain extended hydroxy-carboxylic acid/polyoxyalkylene ABA triblocks (abstract). The A block is derived from lactide, glycolic and various lactones (Column 3 lines 31-35), the B block may be polyethylene oxide and the like, and the chain extender may be diacyl halides formed from derivatizing dicarboxylic acids (Column 6 lines 43-44), wherein the dicarboxylic acids may be sebacic and the like (Column 14 lines 35-50). The molar ratio of the chain extender to the ABA copolymer is 1:2 to 2:1 (Column 9 lines 48-50). The catalyst used to react the diol and lactone may be stannous octoate, which is a synonym for tin-2-ethylhexanoate (see the attached chemical data sheet). The elements above meet the requirements of claims 1, 2, 3, 7, 13, 14, 15, 16, 20, 21, 22, 25, 26, 27, 28, 29, 30, 31 and 32. Since the composition requirements are met the properties of claims 4 and 18 are deemed inherently met by the composition. The A block may have 4-50 units therein (Column 4 line 45), as required by claims 5 and 6 and since the molar ratio and difunctionality of the coupling agent is met, the x macromeric units are found to be encompassed by the teachings of Cohn, as further required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e 2 A

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units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, 8/10=80%) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12. The MW of the triblock spans 1,000-30,000, and as such when one chain extends with a 1:1 molar ratio one would expect a doubling of the MW, encompassing the range of claim 17. The resulting compositions are used to deliver bioactive compositions such as antibodies and the like (Column 16 lines 28-56). There is no structural limitation of device or process limitation of the adaptation and as such the delivery vehicle described by Cohn is found to meet the limitations of claims 33-36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Spinu (US 202413) in view of Cohn (US 5711958).

Spinu includes elements as set forth above. Spinu discloses ABAN type degradable molded resins. Spinu does not disclose the use of bioactive agents with said resin.

Cohn discloses methods for reducing post surgical adhesion formation. Cohn discloses using ABA triblocks comprising lactic acid-A blocks and diol-based B blocks (Column 3 lines 28-46), the same structure and monomer elements used by Spinu. Cohn also discloses linking the blocks together with acyl acids to form ABAN type degradable resins (Column 3 line 50). Cohn and Spinu thusly disclose very similar polymer compositions. Cohn discloses that such compositions are suitable for use in vivo to prevent surgical adhesion, and further discloses the incorporation of bioactive agents such as antibodies and the like (Column 16 lines 28-56) to further promote wound healing.

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In light of such it would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Spinu in surgical healing, as taught by Cohn, since it is known in the art to be useful for such. Additionally, it would have been obvious to one of ordinary skill to include in Spinu the use of the bioactive agents taught by Cohn to enhance the healing of the surgical wounds to which the composition was applied to.

13. Claims 15, 16, 17, 21, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler in view of Spinu.

Fowler includes elements as set forth above. Fowler discloses the ABA type polymers further reacted with a diisocyanates to form higher molecular weight products (Column 9 lines 19-24). Fowler does not disclose diacyl halide chain extenders nor the end molecular weight of the chain extended polymer, as further required by the above claims.

Spinu includes elements as set forth above. Spinu discloses very similar, if not the same, ABA type polymers further chain extended. The chain extension occurs with either diisocyanates or diacyl chlorides containing 8-20 carbon atoms (Column 5 lines 14-15). Spinu thusly teaches the functional equivalence of said chain extenders.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Fowler the use of diacyl chlorides having 8-20 carbon atoms, as taught by SPinu, since they are recognized in the art as functional equivalents to diisocyanate chain extenders.

Fowler does not disclose the end MW of the chain extended polymer, Spinu discloses that an end MW of 10,000-250,000 is suitable for use a general elastomeric applications (Column 5 lines 31-32), the same end use disclosed by Fowler (Column 1 line 16). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297

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(1945), in light of such and in light of the similar uses disclosed in Fowler and Spinu, it would have been obvious to one of ordinary skill to have an end MW of 10,000-250,000 to obtain an elastomeric polymer suitable for the intended use therein.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler and McLain (US 5028667).

Fowler includes elements as set forth above. Fowler discloses the use of 2-ethylhexanoic acid and the like as a catalyst (Column 8 line 41) but does not disclose the catalysts of claim 26.

McLain discloses the living polymerization of lactone, the same polymerization occurring in Fowler. McLain discloses the use of oxides of yttrium and other rare earth metals (Column 5 lines 5-19). Said catalysts result in living polymerization, which is characterized by yielding narrow MW distributions, and allows the polymerized lactone to be stored under inert conditions and allows it to be further polymerized with another monomer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include the yttrium oxide catalysts of McLain in the composition of Fowler in order to obtain a narrow MW distribution in the resulting polymer composition.

15. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Fowler (US 2977385) in view of Cohn (US 5711958).

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Fowler includes elements as set forth above. Fowler discloses ABAN type degradable molded resins. Fowler does not disclose the use of bioactive agents with said resin.

Cohn discloses methods for reducing post surgical adhesion formation. Cohn discloses using ABA triblocks comprising lactic acid-A blocks and diol-based B blocks (Column 3 lines 28-46), the same structure and monomer elements used by Fowler. Cohn also discloses linking the blocks together with acyl acids to form ABAN type degradable resins (Column 3 line 50). Cohn and Fowler thusly disclose very similar polymer compositions. Cohn discloses that such compositions are suitable for use in vivo to prevent surgical adhesion, and further discloses the incorporation of bioactive agents such as antibodies and the like (Column 16 lines 28-56) to further promote wound healing.

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In light of such it would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Fowler in surgical healing, as taught by Cohn, since it is known in the art to be useful for such. Additionally, it would have been obvious to one of ordinary skill to include in Fowler the use of the bioactive agents taught by Cohn to enhance the healing of the surgical wounds to which the composition was applied to.

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16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler.

Cohn includes elements as set forth above. Cohn discloses the use of various lactides and caprolactones but does not disclose the use of substituted lactones.

Fowler includes elements as set forth above. Fowler discloses similar ABA type lactide polymers further extended with diisocyanates. Fowler discloses the use of caprolactones and substituted caprolactones (Column 1 line 56-Column 2 line 5). Fowler thusly teaches the functional equivalence of said lactones.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Cohn the use of the substituted caprolactones taught by Fowler since they are recognized in the art as functional equivalents of unsubstituted caprolactones.

17. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler.

Cohn includes elements as set forth above. Cohn discloses various EO/LA ratios however Cohn does not disclose the molar ratio of the reactants.

Fowler includes elements as set forth above. As set forth, Cohn and Fowler disclose similar chain extended lactone ABA polymers. Fowler discloses that one can control the average molecular weight of the product by preselecting the molar proportions, or ratio, of lactone to initiator (diol). For example, if one

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desires a MW 10 times larger than the initial MW the proportions of lactone to initiator are 10:1 (Column 10 lines 60-75). Fowler teaches that higher MW polymers have greater elasticity (Column 11 line 20). Fowler thusly teaches the choice of molar ratio to be a result effective variable.

It would have been obvious to one of ordinary skill in the art at the time of the invention to manipulate the ratios taught in Cohn, as taught by Fowler, in order to obtain the desired end molecular weight to obtain the desired elasticity and tensile strength properties.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "X" reference US 5346966 is similar in content to Spinu set forth above (also an "X" reference) and as such an additional rejection in view of '966 was deemed unnecessary at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796